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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/076,069	02/15/2002	Roland Jurecic	39532-176599	8513

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EXAMINER

BERTOGLIO, VALARIE E

ART UNIT PAPER NUMBER

1632

DATE MAILED: 04/04/2003

10

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/076,069

Applicant(s)

JURECIC ET AL.

Examiner

Valarie Bertoglio

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 February 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) 11-22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☒ Claim(s) 5 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 February 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 7.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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Applicant's election without traverse of Group I, claims 1-10 and specie SEQ ID NO:1 in Paper No. 9 is acknowledged.

Claims 11-22 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Claims 1-10 will be examined as they relate to the elected specie SEQ ID NO:1.

Claim Objections

Claim 5 is objected to because of the following informalities:

Claim 5 ends with improper punctuation comprising two periods.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-4, 6-8 and 10 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims encompass 1) any isolated nucleic acid that is at least 85%, 90%, 95% or 99% identical to SEQ ID NO:1 or a sequence that is complementary thereto, and 2) an isolated nucleic acid that is at least 90%, 96%, 98% or 100% identical to a sequence of at least 50 nucleotides or a sequence that is complementary thereto. Claims 1-4 and 6-10 encompass huge genera of nucleic acids that can vary in as much as 15% of the sequence of SEQ ID NO:1 or can comprise as little as 50 nucleotides sharing at least 90% identity to SEQ ID NO:1. Claims 1-5 encompass nucleic acids encoding polypeptide fragments encoded by SEQ ID NO:1. The

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disclosure does not describe any of the nucleotides encompassed by these claims other than SEQ ID NO:1. Other sequences described in the specification include nucleic acids encoding for the human and zebrafish Hepp proteins. These nucleic acids have significantly less than 85% identity to SEQ ID NO:1.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states that “applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the ‘written description’ inquiry, whatever is now claimed.” (See page 1117.) The specification does not “clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed.” (See *Vas-Cath* at page 1116).

With the exception of the sequences referred to above, the skilled artisan cannot envision the detailed chemical structure of the encompassed polynucleotides, and therefore conception is not achieved regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The nucleic acid itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Therefore, only SEQ ID NO:1 and sequences that due to the degeneracy of the genetic code encodes a protein product identical to that encoded by SEQ ID NO:1, but not the full breadth of the claim meets the written description provision of 35 U.S.C. §112, first paragraph.

Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

Claims 1-8 and 10 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated nucleic acid comprising SEQ ID NO:1 and a sequence that due to the degeneracy of the genetic code encodes a protein product identical to that of SEQ ID NO:1 and an isolated nucleic acid that is identical to at least 50 contiguous nucleotides of SEQ ID NO:1, does not reasonably provide enablement for an isolated nucleic

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acid comprising a sequence that encodes any polypeptide fragment encoded by SEQ ID NO:1 or for any and all isolated nucleic acids that are less than 100% identical to SEQ ID NO:1. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Claims 1-5 encompass a nucleic acid encoding any polypeptide product that is identical to that encoded by SEQ ID NO:1. These claims encompass any and all fragments of the full-length protein encoded by SEQ ID NO:1. The specification does not teach the function for each and every polypeptide product encompassed by the claims. Therefore, it would require one of skill in the art undue experimentation to determine how to use each and every nucleic acid encompassed by claims 1-5.

Claims 1-4 encompass any nucleic acid having at least 85% identity to SEQ ID NO:1. The specification fails to describe the function of any and all nucleic acids with greater than 85% but less than 100% identity with SEQ ID NO:1. Claims 1-4 encompass a huge genera of nucleic acids that can vary in as much as 15% of the sequence of SEQ ID NO:1. Alteration could comprise changes including deletions, insertions or base changes interspersed throughout any 15% of the nucleic acid. The function of all of these variants of SEQ ID NO:1 is not known and cannot be predicted. Therefore, without undue experimentation, one of skill in the art at the time of filing would not know how to use the nucleic acids that are broadly encompassed by the claims.

Claims 6-8 and 10 encompass isolated nucleic acids that are at least 90% identical to at least 50 contiguous nucleotides of SEQ ID NO:1. While one of skill in the art would know how to use a nucleic acid that is identical to a 50 nucleotide fragment of SEQ ID NO:1, it is not clear that one would know how to use any and all such fragments that are not 100% identical to the corresponding fragment of SEQ ID NO:1. It would require one of skill in the art undue

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experimentation to determine which, if any, of the huge genera of nucleic acids encompassed by the claims have use as primers, probes, homology arms to direct homologous recombination or any other use. Therefore, the specification fails to enable one to use nucleic acids that are at least 90% identical, but less than 100% identical, to at least 50 contiguous nucleotides of SEQ ID NO:1.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is unclear if the "identical polypeptide product" in claims 1-4 is referring to the protein product encoded by SEQ ID NO:1 or to protein product encoded by the nucleic acid comprising a sequence that is at least 85% (claim 1), 90% (claim 2), 95% (claim 3) or 96% (claim 4) identical to SEQ ID NO:1.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1) Claims 1-5 are rejected under 35 U.S.C. 102(a) as being anticipated by Yahyawi (December 2000, Genbank Accession Number BF607870).

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Claims are directed to isolated nucleic acids comprising a sequence that due to the degeneracy of the genetic code encodes a polypeptide identical to a polypeptide product of SEQ ID NO:1. Claims encompass a polypeptide fragment encoded by SEQ ID NO:1.

Yahyawu teaches a nucleic acid that encodes polypeptides that are identical to polypeptides encoded by SEQ ID NO:1 (see attached sequence alignment).

2) Claims 6-10 are rejected under 35 U.S.C. 102(a) as being anticipated by Kargul (January 2001, Genbank Accession Number BG069072) or Kargul (January 2001, Genbank Accession Number BG082096) or Arakawa (June 2000, Genbank Accession Number BB055758).

Claims are directed to isolated nucleic acids comprising a sequence at least 90% (claim 6), 96% (claim 7), 98% (claim 8) identical to, or 100% identical to (claim 9), at least 50 contiguous nucleotides in SEQ ID NO:1 or an isolated nucleic acid comprising a sequence at least 90% identical to at least 100 contiguous nucleotides of SEQ ID NO:1.

Kargul (January 2001, Genbank Accession Number BG069072) disclosed a stretch of nucleic acids at least 100 nucleotides (697 nucleotides) in length that are 100% identical to SEQ ID NO:1 (see attached sequence alignment).

Kargul (January 2001, Genbank Accession Number BG082096) disclosed a stretch of nucleic acids at least 100 nucleotides in length that are 100% identical to SEQ ID NO:1 (see attached sequence alignment).

Arakawa (June 2000, Genbank Accession Number BB055758) disclosed a stretch of nucleic acids at least 100 nucleotides in length that are 100% identical to SEQ ID NO:1.

3) Claims 1-5 are rejected under 35 U.S.C. 102(b) as being anticipated by Gallatin (1998, USPN 5,831,029, SEQ ID NO: 45).

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Claims are directed to isolated nucleic acids comprising a sequence that due to the degeneracy of the genetic code encodes a polypeptide identical to a polypeptide product of SEQ ID NO:1. Claims encompass a polypeptide fragment encoded by SEQ ID NO:1.

Gallatin teaches a nucleic acid that encodes polypeptides that are identical to polypeptides encoded by SEQ ID NO:1 (see attached sequence alignment).

Conclusion

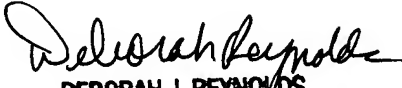
No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Valarie Bertoglio whose telephone number is 703-305-5469. The examiner can normally be reached on 7:00-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds can be reached on 703-305-4051. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

Valarie Bertoglio
Patent Examiner


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